



RULE-MAKING ORDER

(RCW 34.05.360)

CR-103 (7/22/01)

Agency: Health Care Authority Administrative Order #03-02

- ☒ Permanent Rule
☐ Emergency Rule
☐ Expedited Rule Making

(1) Date of adoption: February 12, 2004

(2) Purpose: These rules govern prescription drug programs established pursuant to chapter 41.05 RCW and are necessary to implement SB 6088 (Chapter 29, Laws of 2003), as codified at RCW 41.05.021. This new administrative chapter 182-50 WAC is set aside for management of the prescription drug programs administered by the Health Care Authority.

(3) Citation of existing rules affected by this order:

Repealed:
Amended:
Suspended:

(4) Statutory authority for adoption: RCW 41.05.160; SB 6088, Section 10.

Other Authority:

PERMANENT RULE ONLY (Including Expedited Rule Making)

Adopted under notice filed as WSR 04-01-186 on 12/23/03.

Describe any changes other than editing from proposed to adopted version:

EMERGENCY RULE ONLY

Under RCW 34.05.350 the agency for good cause finds:

- ☐ (a) That immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest.
- ☐ (b) That state or federal law or federal rule or a federal deadline for state receipt of federal funds requires immediate adoption of a rule.

Reasons for this finding:

(5.3) Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?:

☐ Yes ☒ No If Yes, explain:

(6) Effective date of rule:

Permanent Rules

- ☒ 31 days after filing
☐ Other (specify) _____*

*(If less than 31 days after filing, specific finding in 5.3 under RCW 34.05.380(3) is required)

Emergency Rules

- ☐ Immediately
☐ Later (specify) _____

CODE REVISER USE ONLY

FILED WITH THE CODE REVISER 2/23/04

TIME: 2:49 P.M.

WSR 04-06-021

Name (Type or Print)
Melodie Bankers

Signature

Title
Rules Coordinator

Date
2/18/04

(COMPLETE REVERSE SIDE)

**Note: If any category is left blank, it will be calculated as zero.
No descriptive text.**

Count by whole WAC sections only, from the WAC number through the history note.
A section may be counted in more than one category.

The number of sections adopted in order to comply with:

Federal statute:	New	_____	Amended	_____	Repealed	_____
Federal rules or standards:	New	_____	Amended	_____	Repealed	_____
Recently enacted state statutes:	New	_____	Amended	_____	Repealed	_____

The number of sections adopted at the request of a nongovernmental entity:

New	_____	Amended	_____	Repealed	_____
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The number of sections adopted in the agency's own initiative:

New	<u>8</u>	Amended	_____	Repealed	_____
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The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New	_____	Amended	_____	Repealed	_____
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The number of sections adopted using:

Negotiated rule making:	New	_____	Amended	_____	Repealed	_____
Pilot rule making:	New	_____	Amended	_____	Repealed	_____
Other alternative rule making:	New	<u>8</u>	Amended	_____	Repealed	_____

Chapter 182-50 WAC

PRESCRIPTION DRUG PROGRAMS

NEW SECTION

WAC 182-50-001 Authority and purpose. RCW 41.05.021 (1)(a)(iii) and 70.14.050 authorize the administrator to establish an independent Washington state pharmacy and therapeutics committee within the health care authority to evaluate available evidence of the relative safety, efficacy and the effectiveness of prescription drugs within a class of prescription drugs, in the development of an evidence-based prescription drug program for participating state purchased health care programs. This section requires the administrator to adopt rules governing practitioner endorsement and use of any preferred drug list developed as part of the prescription drug program.

NEW SECTION

WAC 182-50-005 Definitions. When used in this chapter:

(1) "Appointing authority" shall mean the following persons acting jointly: The administrator of the health care authority, the secretary of the department of social and health services, and the director of the department of labor and industries.

(2) "Committee" means the independent Washington state pharmacy and therapeutics committee created by RCW 41.05.021 (1)(a)(iii) and 70.14.050. At the election of the department of social and health services, the committee may serve as the drug use review board provided for in WAC 388-530-1850.

(3) "Drug" means the term as it is defined in RCW 69.41.010 (9) and (12).

(4) "Endorsing practitioner" means a practitioner who has reviewed the preferred drug list and has notified the health care authority that he or she has agreed to allow therapeutic interchange of a preferred drug for any nonpreferred drug in a given therapeutic class.

(5) "Practitioner" means a health care provider, except a veterinarian, as defined at RCW 18.64.011(9).

(6) "Preferred drug" means a drug selected by the appointing authority for inclusion in the preferred drug list used by applicable state agencies for state purchased health care programs.

(7) "Preferred drug list" or "PDL" means the list of drugs selected by the appointing authority to be used by applicable state agencies as the basis for the purchase of drugs in state purchased health care programs.

(8) "Prescription" has the meaning set forth in RCW 18.64.011(8).

(9) "Refill" means the continuation of therapy with the same drug (including the renewal of a previous prescription or adjustments in dosage) when a prescription is for an antipsychotic, antidepressant, chemotherapy, antiretroviral, or immunosuppressive drug.

(10) "State purchased health care" has the meaning set forth in RCW 41.05.011(2).

(11) "Therapeutic alternatives" are drug products of different chemical structure within the same pharmacologic or therapeutic class and that are expected to have similar therapeutic effects and safety profiles when administered in therapeutically equivalent doses.

(12) "Therapeutic interchange" means to dispense, with the endorsing practitioner's authorization, a therapeutic alternative to the prescribed drug.

NEW SECTION

WAC 182-50-010 Purpose of the pharmacy and therapeutics committee. The purpose of the committee is to evaluate the available evidence of the relative safety, efficacy, and effectiveness of prescription drugs within a class of prescription drugs and make recommendations to the appointing authority for its deliberation in the development of the preferred drug list established in RCW 70.14.050.

NEW SECTION

WAC 182-50-015 Open Public Meetings Act and Administrative Procedure Act; exception as technical review committee. (1)

Meetings of the pharmacy and therapeutics committee shall in all respects comply with the provisions of the Open Public Meetings Act, chapter 42.30 RCW, and shall be subject to the provisions of the Administrative Procedure Act, chapter 34.05 RCW, as applicable.

(2) The pharmacy and therapeutics committee shall constitute a technical review committee created to facilitate the development, acquisition, or implementation of a preferred drug list, for the purposes of state purchased health care under RCW 41.05.026, and as such may hold an executive session in accordance with chapter 42.30 RCW during any regular or special meeting to discuss information submitted in accordance with RCW 41.05.026 (1) through (5).

NEW SECTION

WAC 182-50-025 Membership and qualifications of pharmacy and therapeutics committee. (1) The committee shall consist of no fewer than ten members appointed by the appointing authority.

(2) The appointing authority has the sole right to appoint committee members and may terminate appointment of any member at any time during the term.

(3) The appointing authority will make appointments to the committee from a pool of interested applicants. Interested persons will be provided an opportunity to submit applications to the appointing authority.

(4) Members shall enter into an agreement with the health care authority at the time of their appointment to the committee and shall act in accordance with all of its terms and conditions. Failure to do so may result in termination of the appointment.

(5) The membership composition at all times shall be consistent with applicable federal requirements under the Federal Social Security Act, Title 19 § 1927 and the requirements of the department of social and health services medical assistance administration for its drug utilization review board. Therefore, pharmacists and physicians each shall

represent at least thirty-one percent, but no more than fifty-one percent of committee membership respectively.

(6) Members must be actively practicing in their clinical area of expertise throughout the entire term of their appointments.

(7) Members must have knowledge and expertise in one or more of the following:

(a) Clinically appropriate prescribing of covered outpatient drugs;

(b) Clinically appropriate dispensing and monitoring of covered outpatient drugs;

(c) Drug use review;

(d) Medical quality assurance;

(e) Disease state management; or

(f) Evidence-based medicine.

(8) Members of the committee shall not be employed by a pharmaceutical manufacturer, a pharmacy benefits management company, or by any state agency administering state purchased health care programs during their term shall not have been so employed and for eighteen months prior to their appointment.

(9) A member shall not have a substantial financial conflict of interest including any interest in any pharmaceutical company, including the holding of stock options or the receipt of honoraria or consultant moneys. The appointing authority in its sole discretion may disqualify any potential member if it determines that a substantial conflict of interest exists.

(10) As part of the application process, prospective committee members shall complete a conflict of interest disclosure form, provided by the appointing authority, and after appointment, annually by July 1st of each year. Members must keep their disclosure statements current and provide updated information whenever circumstances change.

(11) Committee members must agree to keep all proprietary information confidential.

NEW SECTION

WAC 182-50-030 Period of appointment. (1) Members shall be appointed to a term of three years and shall serve until a successor is duly appointed. A member may be reappointed to one additional three-year term for a total of six years. One year after the end of a six-year term, a person is eligible for appointment to one additional three-year term.

(2) Committee members serve staggered three-year terms. Of

the initial appointees, in order to provide for staggered terms, some members may be appointed initially for less than three years. If the initial appointment is for less than twenty-four months, that period of time shall not be counted toward the limitation of years of appointment described in subsection (1) of this section.

(3) Vacancies on the committee will be filled for the balance of the unexpired term from nominee lists for the appropriate committee category as provided under WAC 182-50-025.

(4) Members of the committee will be compensated for participation in the work of the committee in accordance with a personal services contract executed after appointment and prior to commencement of activities related to the work of the committee.

NEW SECTION

WAC 182-50-035 Duties. Committee members shall:

(1) Select a chair and a vice-chair from among the committee membership.

(2) Meet at least quarterly and may meet at other times at the discretion of the chair.

(3) Adopt a plan of operation that sets forth the policies and procedures established by the committee to develop an evidence-based prescription drug program as authorized by state law for approval by the appointing authority.

(4) Operate according to the plan of operation as approved by the appointing authority.

NEW SECTION

WAC 182-50-200 Endorsing practitioner therapeutic interchange program; effect of practitioner's endorsing status; dispense as written instructions. (1) When filling

prescriptions for participating state purchased health care programs, pharmacists shall dispense a preferred drug in place of a drug not included in the preferred drug list in a given therapeutic class whenever pharmacists receive a prescription from an endorsing practitioner except:

(a) If the endorsing practitioner determines the nonpreferred drug is medically necessary by indicating "dispense as written" on the prescription; or

(b) If the prescription is a refill of an antipsychotic, antidepressant, chemotherapy, antiretroviral, or immunosuppressive drug.

(2) When a therapeutic interchange is made, the pharmacist shall notify the endorsing practitioner of the specific drug and dose dispensed.

(3) When a nonendorsing practitioner issues a prescription for a drug not included in the preferred drug list, the pharmacist shall dispense the prescribed drug in accordance with the requirements of RCW 69.41.100 through 69.41.180.